

WHAT IS THE IRB & WHAT DO THEY WANT FROM ME?

NCURA REGIONAL CONFERENCE | CHICAGO 2015



Presented by Catherine Anson, John Carroll University



sites.jcu.edu/research

WHO AM I?



- Catherine Anson, MA, CRA, CIM
Director of Sponsored Research
Assistant IRB Chair
canson@jcu.edu
- John Carroll University



DISCLAIMER

SBER

SOCIAL, BEHAVIORAL, AND EDUCATION
RESEARCH PROJECTS



It
depends.



TODAY'S PRESENTATION



PART 1: HISTORICAL PERSPECTIVE

- Brief outline describing the timeline leading up to federal human subject regulations
- Brief info on the Federal Regulations

PART 2: WHAT IS THE IRB?

- Function of IRBs
- How the IRBs do their job

PART 3: WHAT DO THEY WANT FROM ME?

- What IRBs need from researchers

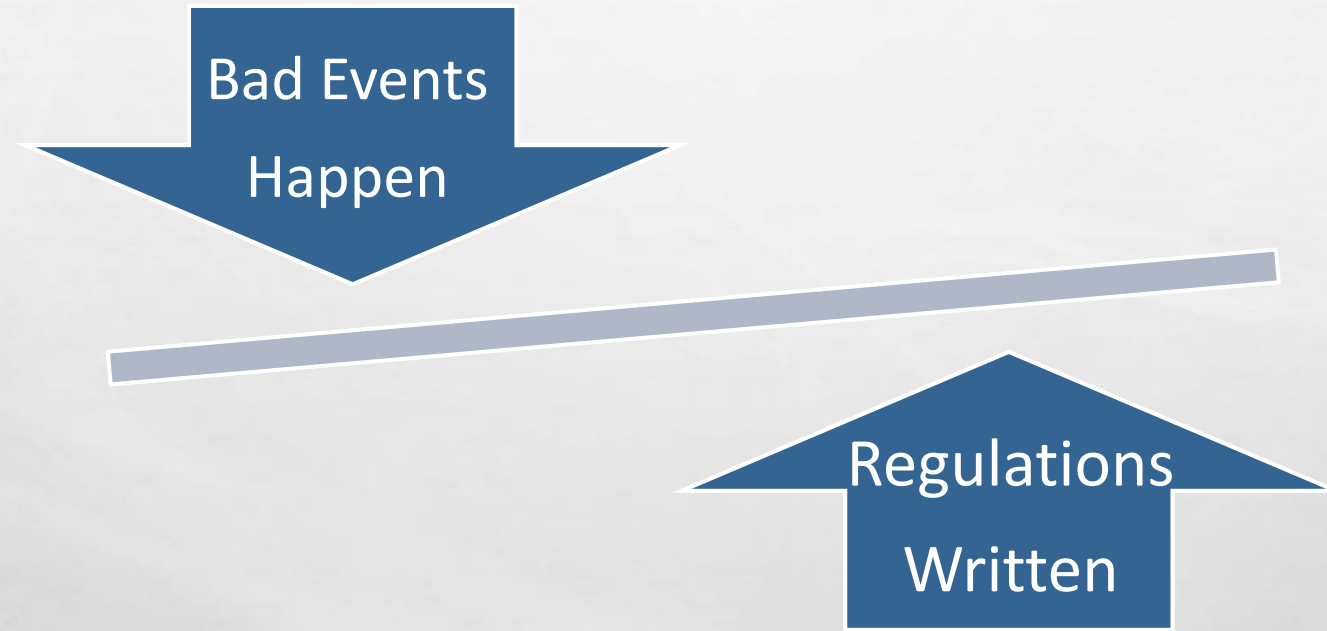
LEARNING OBJECTIVES



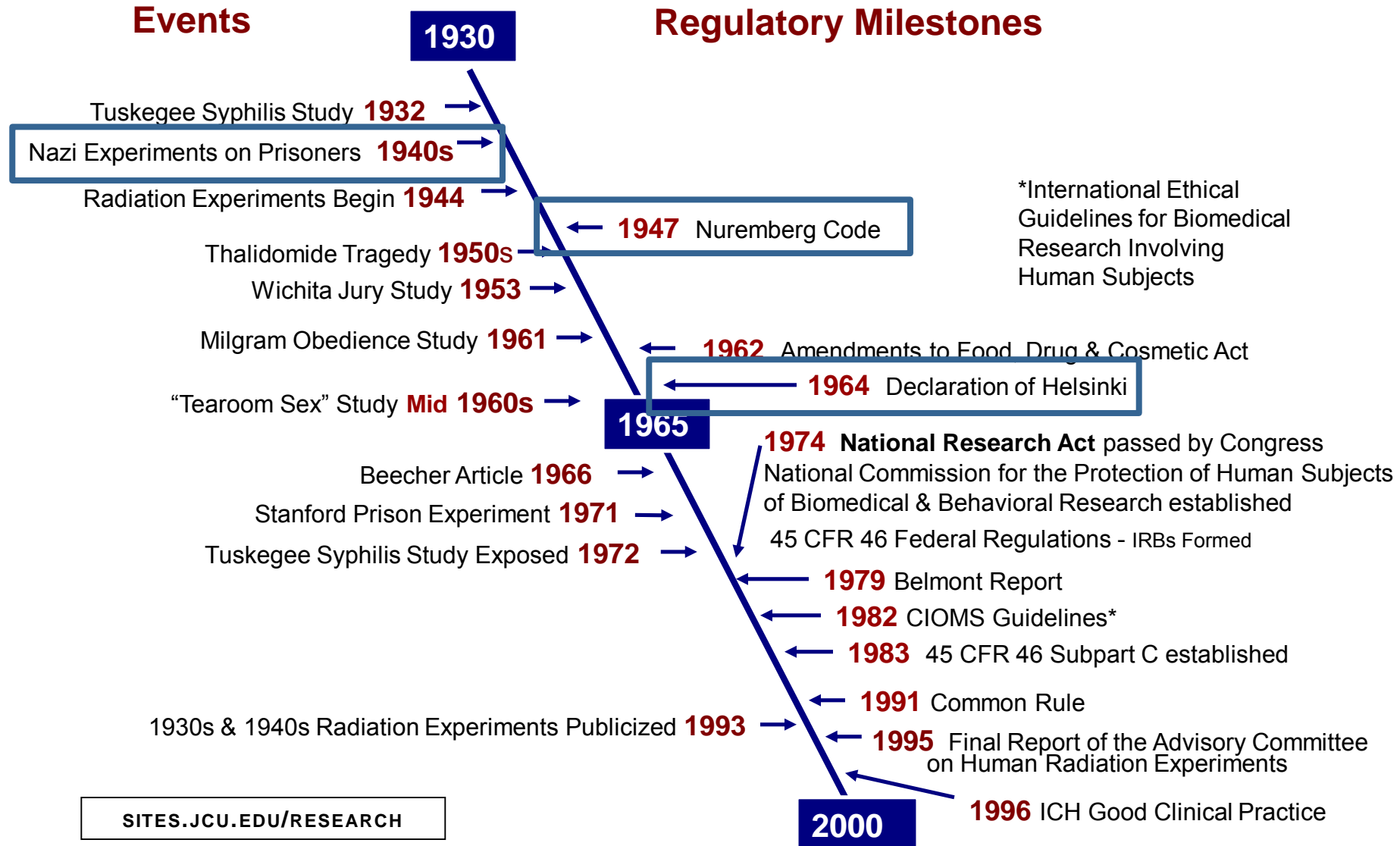
- Identify the historical milestones leading to the formation and revision of federal regulations for the protection of human subjects in research.
- Understand today's ethics climate.
- Apply the regulations to a typical minimal-risk SBER project.

PART 1: HISTORICAL PERSPECTIVE

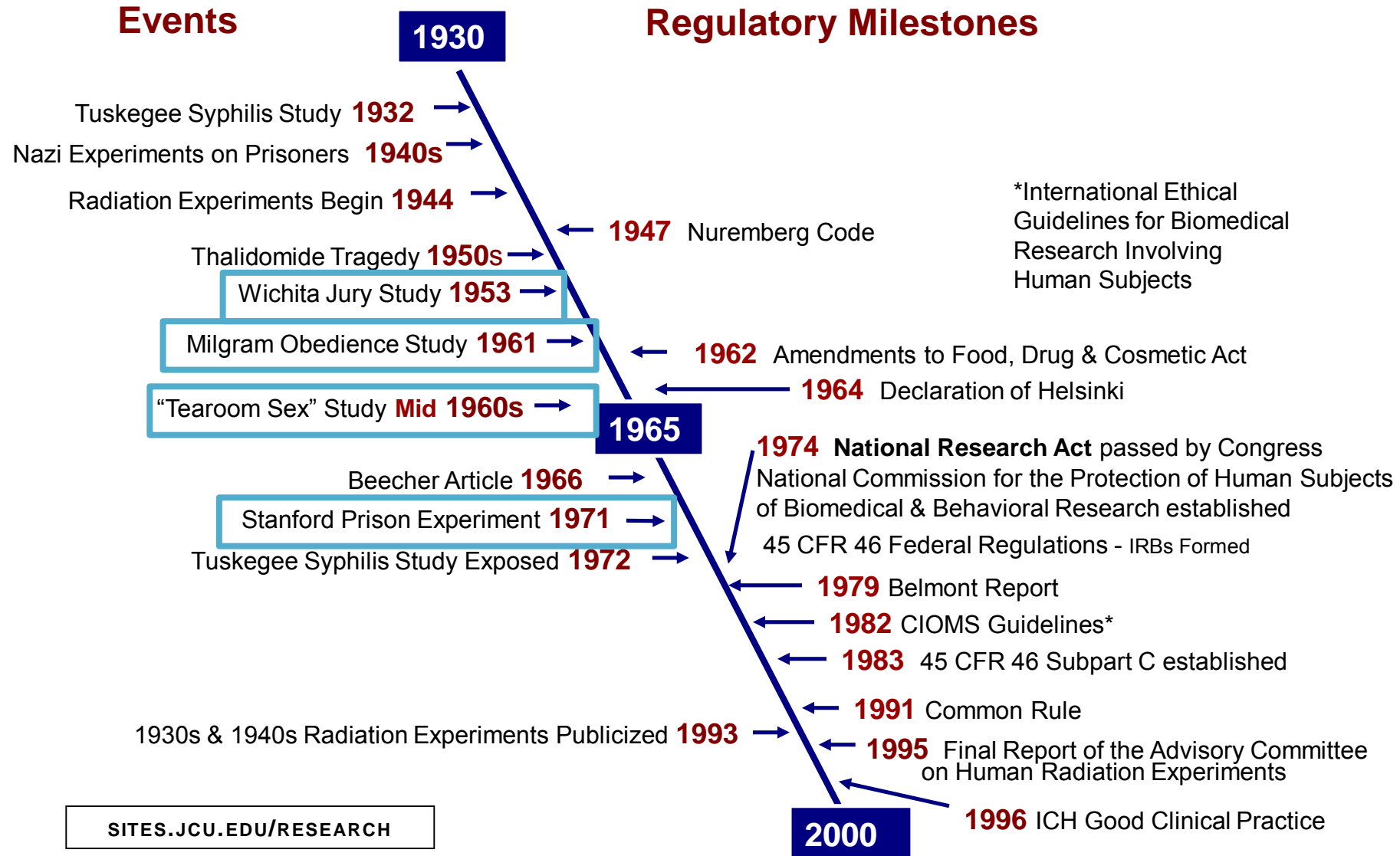
HISTORICAL PERSPECTIVE



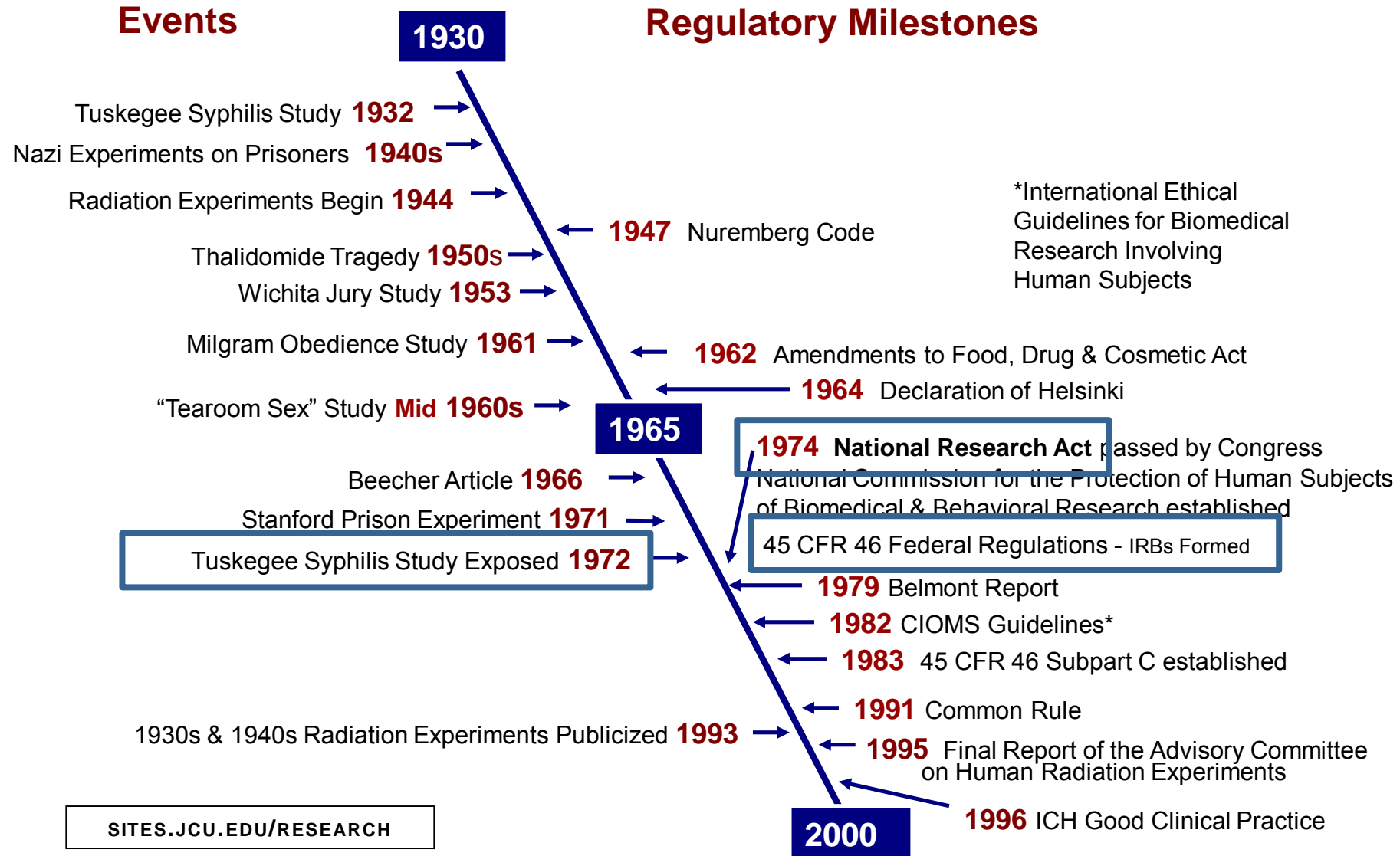
History of Regulations Timeline



History of Regulations Timeline



History of Regulations Timeline



TUSKEGEE SYPHILIS STUDY: 1932-1972



Public health service study using ~400 poor, uneducated, African-American sharecroppers.

- Withheld information
- Harm to wives and children
- Withheld treatment (1947: penicillin available)
- Study continued under numerous supervisors
- Study received periodic review and approval

CODE OF FEDERAL REGULATIONS

- DHHS: 45 CFR 46 (Code of Federal Regulations, Title 45, Part 46)
 - SUBPART A (1991 COMMON RULE)
 - SUBPART B (PREGNANT WOMEN, FETUSES, NEONATES)
 - SUBPART C (PRISONERS)
 - SUBPART D (CHILDREN)

- FDA: 21 CFR 50

CHECKING THE BOX



BELMONT REPORT



1. RESPECT FOR PERSONS: "Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection" (INFORMED CONSENT)
2. BENEFICENCE, "Maximize possible benefits" of the research while "minimizing possible harms" (RISK/BENEFIT RATIO)
3. JUSTICE, DISTRIBUTION OF THE BURDEN OF RESEARCH (Participants should represent the target population)

PART 2: WHAT IS THE IRB?

WHAT IS AN IRB?



IRB: Institutional Review Board for the protection of human subjects

HSRB: Human Subjects Review Board

IACUC: Institutional Animal Care & Use Committee

RESEARCH ETHICS

IRB COMPOSITION



A GROUP OF AT LEAST 5 PEOPLE:

- 1 NON-SCIENTIST
- 1 SCIENTIST
- 1 COMMUNITY MEMBER
- A MIX OF GENDER, RACE, ETC., VARYING BACKGROUNDS
- A REPRESENTATIVE FROM THE MAJOR SUBJECT POOL
- PROFESSIONAL COMPETENCE & EXPERIENCE
- **“NO IRB MAY CONSIST ENTIRELY OF MEMBERS OF ONE PROFESSION.”**

45 CFR 46.107

OPRR/OHRP



WHAT DOES THE IRB DO?



Reviews and approves research projects that meet the following criteria:

- Informed consent will be sought and appropriately documented.
- Risks to subjects are minimized and are reasonable in relation to anticipated benefits.
- The selection of subjects is equitable.
- There is adequate provision for monitoring the data collected to ensure the safety of subjects, to protect the privacy of subjects, and to maintain the confidentiality of the data.

45 CFR 46.111(a)

WHAT FALLS UNDER IRB JURISDICTION?*



Research

Human
Subjects

develop/contribute
to generalizable
knowledge

*According to 45 CFR 46

FEDERAL DEFINITIONS



Research

- “Research means a systematic investigation, including research development, testing and evaluation”

Human Subject

- “a living individual about whom an investigator... obtains: (1) Data through intervention or interaction...or (2) Identifiable private information...”

Generalizable

- ????

45 CFR 46.102

4 RESEARCH CATEGORIES



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
---	---------------	------------------	-------------------

4 RESEARCH CATEGORIES



**Not Under IRB
Jurisdiction**

Exempt

Expedited

Full Board

3 CONDITIONS

Research

Human Subjects

Generalizable

NO IRB REVIEW



- Journalism projects (newspaper articles, investigative journalism, filmed documentaries)
- Biographies
- Program Reviews (done for the purposes of improving the program)
- Case Studies

ACTIVITY



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board

EXAMPLE 1



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
----------------------------	--------	-----------	------------

A management professor wants to send out a survey to CEOs to ask them their opinions on leadership. Demographics on their education, salary, and employment history are requested. The data will be analyzed and the results will be published in a scholarly journal.

EXAMPLE 2



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
----------------------------	--------	-----------	------------

A student in environmental studies wants to survey managers of companies providing tree cutting services to collect statistics on employee accidents. The data will be compared to previous studies to determine safety trends and the results will be published in a scholarly article.

EXAMPLE 3



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
----------------------------	--------	-----------	------------

A professor in the Education department wants to conduct focus groups composed of high school principals regarding their opinion of best practices for new teachers. The results will be analyzed and used to improve the department's curriculum.

EXAMPLE 4



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
----------------------------	--------	-----------	------------

A student in the Communications department wants to conduct interviews with fellow students regarding their sexual history and use of drugs. The results of the study will be published in the campus newspaper.

4 RESEARCH CATEGORIES



**Not Under IRB
Jurisdiction**

Exempt

Expedited

Full Board

3 CONDITIONS

Research

Human Subjects

Generalizable

RETROSPECTIVE APPROVAL





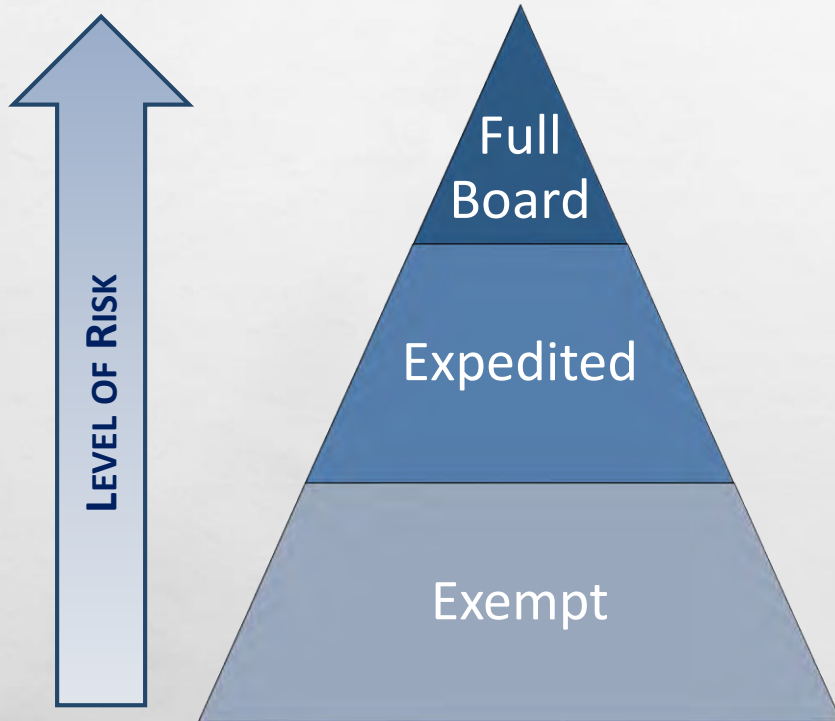
PART 3: WHAT DO THEY WANT FROM ME?

TRIAGE



Not Under IRB Jurisdiction	Exempt	Expedited	Full Board
<ul style="list-style-type: none">• Journalism• Biographies• Case Studies• Internal Program Review	<p>“Unless otherwise required ..., research activities are exempt from this policy if they fall in one or more of the following categories...”</p> <p>[45 CFR 46.101(b)]</p>		<ul style="list-style-type: none">• Higher risk• Doesn't fit into any of the other categories

HIERARCHY OF CATEGORIES



Higher risk; doesn't fit in any other category

Surveys; focus groups; program evaluations; etc.

Surveys; interviews; public observations

MINIMAL RISK



“Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life [**of a healthy person**] or during the performance of routine physical or psychological examinations or tests.”

45 CFR 46.102.(i)

MANAGING RISK



Consider both the degree and the likelihood of risk.

Risk cannot be managed unless it is first recognized by the researcher.

PROJECT 1: BUSINESS SURVEY



A business professor wants to send out a letter to local restaurants stating that his anniversary was ruined last Saturday when their meal made them sick to their stomach.

The purpose of the study is to see how individual owners response to customer complaints. A scholarly article will be written after analyzing the results.

PROJECT 2: BULLYING



A grad student in the Education department wants to study bullying at a local middle school. She has the permission of the principal to conduct the study but she is not affiliated with the school as an employee.

The permission slip and the student survey will be sent home for completion. The survey will collect information on bullying experiences and, for those who indicate yes, whether fellow classmates or teachers have done anything to alleviate the situation.

The permission slip and survey will be returned to the school and turned in to the classroom teacher. The research project will be used as the basis for her master's thesis.

PROJECT 3: LABOR STUDY



A full professor in the Sociology departments wants to survey superintendents of school districts in Ohio. She is working with an adjunct professor who is a superintendent and has access to the list of Ohio superintendents.

No names will be associated with the returned surveys but demographic information is requested. The survey will include questions on job satisfaction, relationships with fellow employees, their perceived effectiveness on the job, and how they discipline students. The purpose of the study is to look at labor relations in school districts.

The results will be published in a scholarly article.

PROJECT 4: WEIGHT GAIN



A psychology student wants to conduct an experiment with female athletes on campus. He wants to weigh them, give them a false weight (higher than their actual weight) and then have them complete mood and confidence questionnaires.

He will compare the results against a control group and present his findings at a regional conference.

PROJECT 5: FOCUS GROUPS



A professor in the Religious Studies department wants to conduct focus groups and personal interviews with parishioners of a local Catholic church which is scheduled to close. The study will capture the personal experiences and opinions. The church has strong ties to the local community and parishioners are upset with the approaching closure.

The professor plans to archive the information in a data bank for use by other scholars who want to study the relationship between the church and its community.

FIRST QUESTIONS

- Is it research?
- Does it involve human subjects?
- What will you do with the results? Will it advance knowledge in the field?
- Is the target group vulnerable?
- What is the level of risk?

TOP TEN IRB REQUESTS



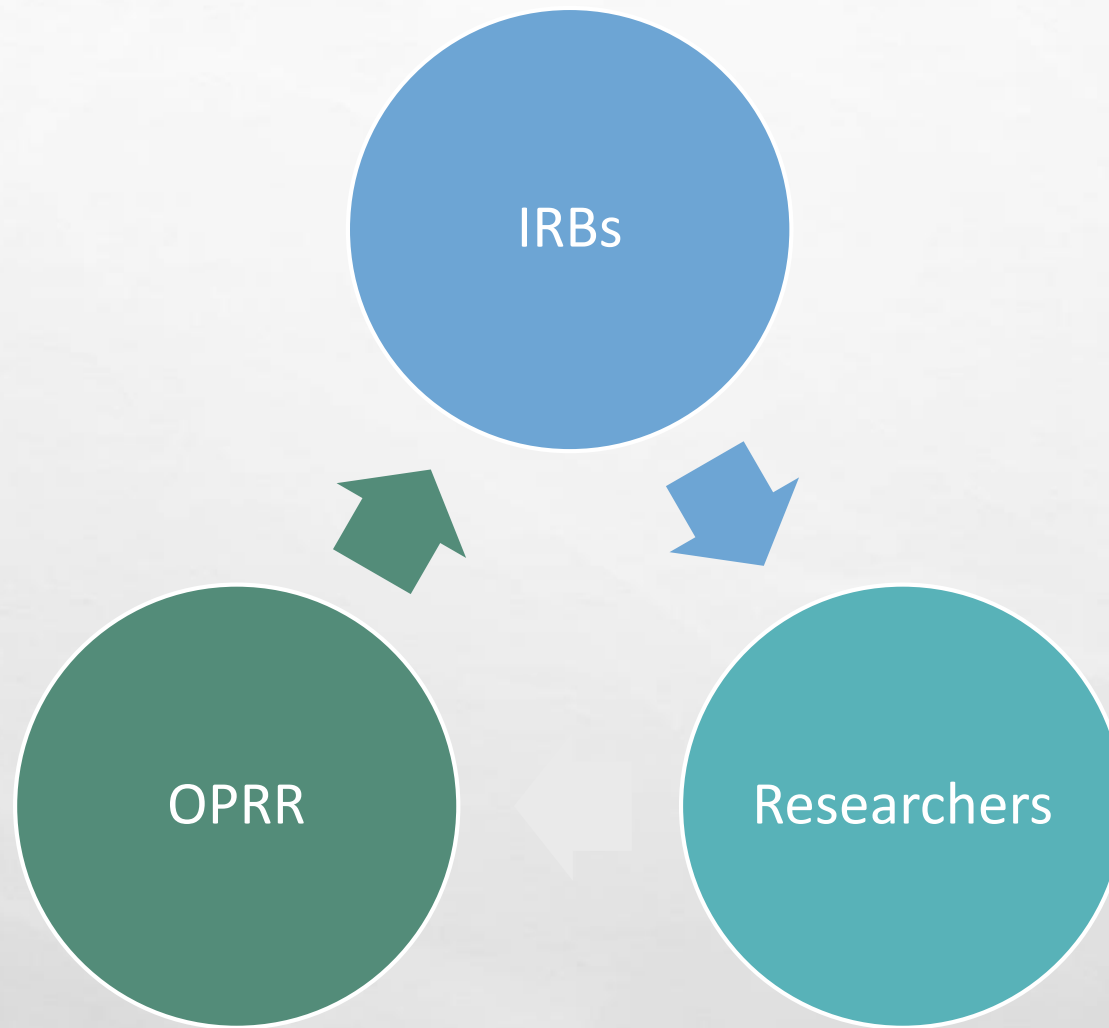
1. A COMPLETE APPLICATION
2. EASY TO READ WITH NO JARGON
3. NO INTERNAL DISCREPANCIES
4. CORRECT USE OF TERMS (ANONYMOUS, CONFIDENTIAL, DECEPTION, CONCEALMENT)
5. READING LEVEL OF CONSENT FORM IS COMPATIBLE WITH TARGET AUDIENCE

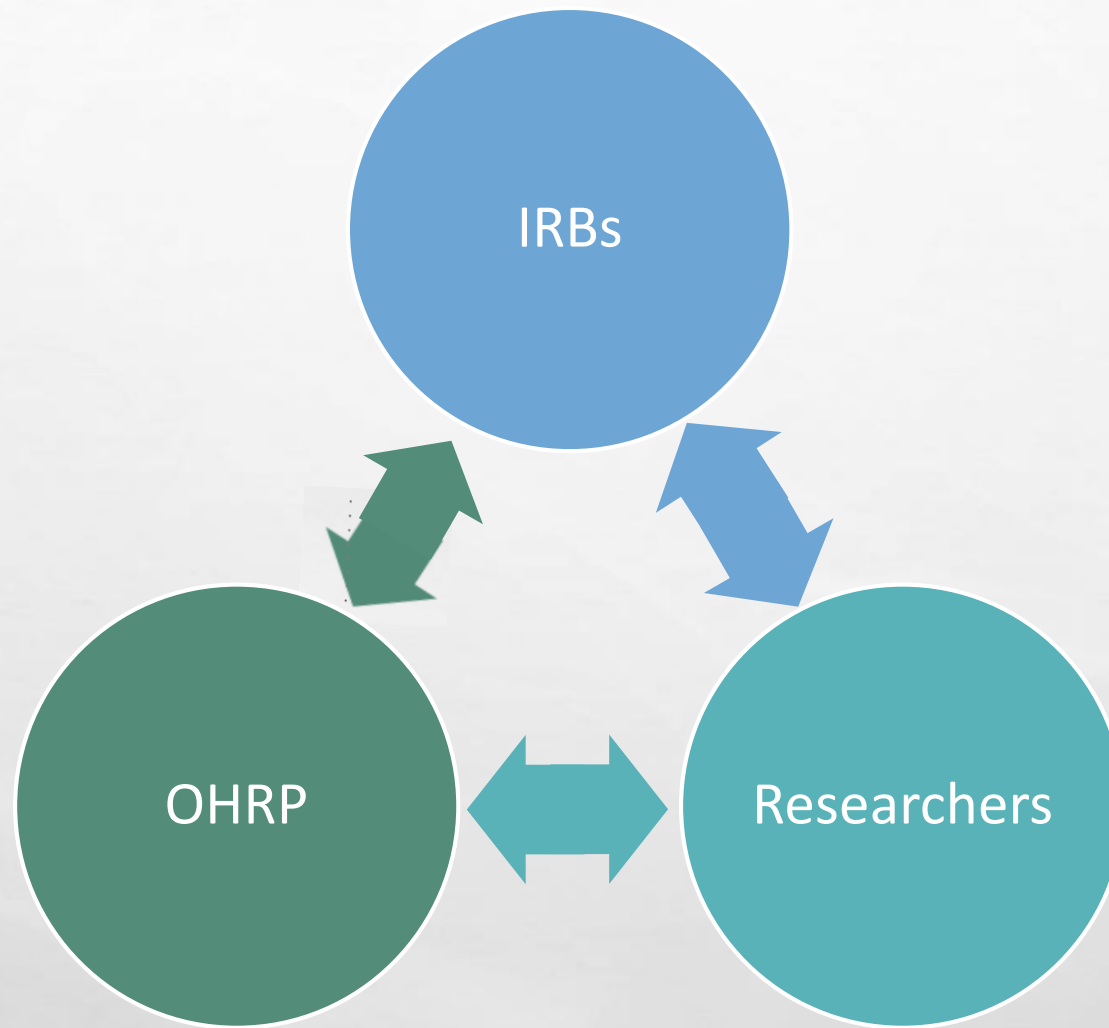
TOP TEN IRB REQUESTS



6. RISK IS ACKNOWLEDGED AND ADDRESSED (MITIGATED).
7. NO GRAMMATICAL OR TYPOGRAPHICAL ERRORS ON CONSENT FORMS OR PUBLIC MATERIALS UNLESS JUSTIFIED IN THE APPLICATION.
8. THE APPLICATION FOR COMPLEX OR MULTI-STAGE PROJECTS HAVE MATERIALS THAT ARE GROUPED AND CLEARLY LABELED.
9. THE APPLICATION IS SUBMITTED IN ADVANCE OF THE START.
10. THE RESEARCHER HAS AN APPROPRIATE PLAN TO CONTACT PARTICIPANTS.

WRAP UP

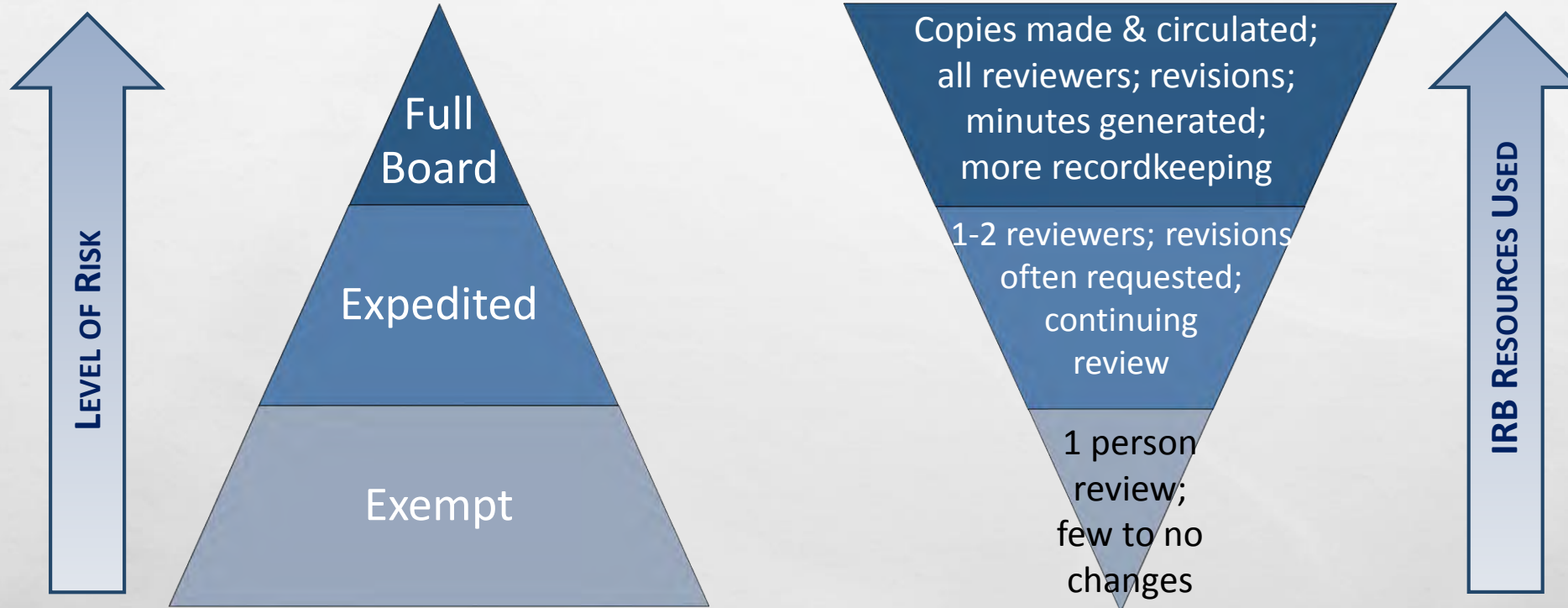




UNCHECKING THE BOX



HIERARCHY OF CATEGORIES



QUOTE



“Dedicated to the protection of human subjects through the application of regulations, ethics, and common sense.”

Erica Heath, CIP
President, IRC